

Tue 2nd August 2022



Today's issue of *PD*

Pharmacy Daily today features four pages of news, plus the August MIMS Update.

NZ Hep C push

PHARMACIES across New Zealand have been enlisted to participate in a new Government-backed "stick it to hepatitis C" testing and awareness campaign.

The promotion launched last Thu to mark World Hepatitis Day, and is part of New Zealand's goal of eliminating hepatitis C as a major public health threat by 2030.

The testing program has been running in 64 Kiwi pharmacies in 2021, with the expansion to now see more pharmacies becoming involved.

The NZ Govt noted that over 200 New Zealanders die of hepatitis each year despite easy test and cure options.

Peak bodies unaware of NVP program

PHARMACY'S peak bodies report having no knowledge about the details of a Philip Morris International (PMI) backed patient support program for nicotine vaping products (NVP).

The scheme is expected to be rolled out by PharmaPrograms, and will allegedly provide fees to pharmacists for referring patients to a doctor to request an NVP, providing education about PMI's VEEV vaping product, and a "dispensing support payment" when they fill new scripts for product, News Limited reported.

A spokesperson for the Pharmaceutical Society of Australia (PSA) said the organisation only became aware of the program vesterday.

"PSA does not support any direct involvement by tobacco companies with pharmacists, or any health professionals for that matter," the spokesperson said.

"PSA also does not condone tobacco companies providing

financial support for continuing professional development (CPD) or any activity."

A spokesperson for the Pharmacy Guild of Australia noted that it had no involvement in the program, but added that the organisation had not pressed for NVP to be made Prescription-Only products.

"The Guild is unaware of the details of the program but it must be noted that prescriptions are required for nicotine products to be used with vaping equipment," the spokesperson said.

"The pharmacist's role is to dispense the medication as prescribed.

"The pharmacist does not have a role in making specific recommendations to doctors in relation to prescribing of nicotine

"The Guild did not request that this product be made prescription only - that is a decision taken by the Therapeutic Goods Administration."

A spokesperson for



PharmaPrograms told **Pharmacy** Daily that "it is important to note that pharmacists are not paid to recommend a product".

"The VEEV Pharmacy Program exists to support patients who have been prescribed nicotine vaping products by an authorised prescriber," the spokesperson said.

"The Federal Government has asked pharmacists to supply vaping products by prescription, and the program aims to support pharmacies in managing safe and effective dispensing of these products, only once a prescription is received."



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Pharmacy must be culturally safe

PHARMACISTS are being urged to embrace the Pharmaceutical Society of Australia's (PSA's) new Guideline for pharmacists supporting Aboriginal and Torres Strait Islander Peoples with medicines management, so they provide culturally safe care.

Launching the guideline at the PSA's conference in Sydney on Sat, Indigenous pharmacist, Associate Professor Faye McMillan (pictured), said it was important that pharmacists practice in a socially just manner.

"We've really been deliberate in the way the guidelines have been set out, to say that they are agnostic, and that they are applicable to every person that works in pharmacy and that works in the pharmacy space - not just the pharmacist," she said.

McMillan stressed that when it comes to the delivery of culturally safe and responsive care, the patient is the person who determines what their experience has been.

"We can obviously stand there and go 'that was not my intention', if somebody tells you that 'I felt uncomfortable, I didn't feel safe', or the other words of 'I felt racism, I experienced racism in your workplace'." she said.

"They're hard things to hear, they're hard things to be reflective of, but we really need to hear these, because it's the experience of the individuals, and when we're saying we are culturally safe practitioners and we are responding to the culture of the people we are working with, then that demonstrates a level of emotional intelligence that allows us to continually reflect on our own practice."

McMillan said the guidelines provide "signposts" for pharmacists to better support Indigenous Australians in a culturally safe environment.

However, she noted that throughout her career she has not



always found the profession to be culturally safe.

"It wasn't until 2019, that I as a Wiradjuri woman felt part of the pharmacy family," she said.

"It wasn't a culturally safe place for me as a First Nations person to be engaged in the profession.

"So I worked in other organisations to try and create the opportunities and the change that I felt was needed in the pharmacy profession, and it has been a hard journey".

CSL seals deal

AUSTRALIAN biotech giant CSL Limited today confirmed it had received all required regulatory clearances necessary for its acquisition of Switzerland's Vifor Pharma.

Completion of the deal is now expected to take place within the next week, with Herve Gisserot appointed to lead the business as General Manager once the acquisition settles.

CSL anticipates it will hold more than 97% of Vifor shares upon completion, and will apply for delisting of the firm on the Swiss Exchange.

Planning for the integration of Vifor into the CSL business is "well advanced" according to CEO Paul Perrault, who said the deal "adds near-term value along with a clear path to long-term sustainable growth" with Vifor's market-leading portfolio of nephrology and iron deficiency products.





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Vax reminders

THE Federal Government has confirmed plans to roll out a text message campaign this month targeting disability support pension and carer payment recipients about the importance of accessing a fourth COVID-19 vaccination.

About one million Australians will receive the so-called "Text2Vax" messages, which will also provide information about the availability of antiviral treatments to treat the ailment.

The Government said the messages had been developed following consultation with people living with disability and their carers.

COVID-19 boosters for this cohort are available via a range of channels including state and territory clinics, GPs and pharmacies.

Palliative care med supplies secured

ACCESS to a key subsidised medication used by palliative care patients has been restored after the sole supplier of the drug left the Australian market last year.

Palliative Care Australia (PCA)
Acting CEO, Margaret Deerain,
noted that while overseas suppliers
have been able to provide access
to hydromorphone oral solution,
through special provisions, the
medication came in significantly
larger bottle sizes, which created a
safety risk.

"Hospital and community pharmacists found themselves stuck in the middle and unable to deliver a medication many people relied on, and one the sector wanted to continue to provide for," she said.

"Pharmacists were unable to split the bottles into smaller quantities and ensure their patients had access to the Pharmaceutical Benefits Scheme (PBS) subsidies. "However, I am pleased to report that the Commonwealth Department of Health has responded to the issue and made adjustments to the Pharmaceutical Benefits Scheme claiming arrangements so that palliative care patients can access the amount of medication they need, while also ensuring greater stewardship and limiting waste of this important medication."

The move to improve access to the medication through the PBS has also been backed by the Society of Hospital Pharmacists of Australia (SHPA) CEO, Kristin Michaels.

"Our hospital pharmacist members who work alongside doctors and nurses to provide safe and quality care for palliative care patients, have prioritised medicines safety and quality use of medicines by supplying smaller bottles of hydromorphone liquid," she said.



"In doing so, they have been forgoing PBS reimbursement for hydromorphone liquid, which costs hundreds of dollars.

"We are very pleased to see the advocacy of PCA and SHPA's Palliative Care Leadership Committee result in a commonsense change to the PBS listing of hydromorphone liquid which will facilitate safe and quality access to a critical medicine for palliative care patients."

Banana Boat batches recalled in USA

EDGEWELL Personal Care
Company has issued a voluntary
nationwide consumer-level recall
of three batches of Banana Boat
Hair & Scalp Sunscreen Spray
SPF30, after an internal review
found some samples of the
product contained trace levels of
benzene.

The US Food & Drug Administration highlighted the move in an update from the company, noting that "while benzene is not an ingredient in any Banana Boat products, the review showed that unexpected levels of benzene came from the propellant that sprays the product out of the can".

The impacted batches are lot codes 20016AF, 20084BF and 21139AF, with Edgewell saying that no other Banana Boat products are in the scope of the recall "and may continue to be used by consumers safely and as intended".

Retailers across the US have been notified of the recall while Edgewell is also offering reimbursement for consumers who purchased impacted items.

Big Data plan for European regulators

THE European Medicines Agency (EMA) has published the "workplan" for its Big Data Steering Group over the next three years, detailing how it plans to further enhance the efficient integration of data analysis into the evaluation of medicinal products.

"Using novel technologies and the evidence generated from big data will benefit public health by accelerating medicine development, improving treatment outcomes and facilitating earlier patient

access to new treatments," the organisation said.

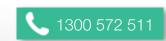
The update lays out timelines for Europe's Data Analysis and Real World Interrogation Network (DARWIN) including predictions that over 100 DARWIN studies will be undertaken annually by 2025.

A data quality framework for the EU regulatory network is to be delivered by the end of the year, and the EMA also foresees the publication of a "good practice guide" on real-world metadata.



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Pharmacy

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Dispensary Corner

AN ELABORATE law enforcement sting in the USA has led to the arrest of a doctor on Florida's Gulf Coast accused of selling "hundreds" of fraudulent prescriptions for people she had never seen.

Court records indicate that 62-year-old Neelam Uppal was charged last week on three counts of trafficking in codeine, and three relating to oxycodone, according to the records of the investigation.

The local sheriff in Pinellas confirmed receipt of an anonymous tip in May which alleged the medico was writing scripts for cash.

Detectives and a confidential informant then posed as customers seeking the medications and allegedly confirmed the scam, with a police spokesperson saying authorities believe the doctor had been "preying on drug addicts for several years".

Just since Jan they allege she sold more than 550 prescriptions for promethazinecodeine cough syrup as well as hundreds more for oxycodone, claiming she was charging US\$450 for an oxy script and US\$650 for codeine syrup.

A search warrant for the doctor's home revealed an alleged cornucopia of items including "prescription pads, patient records, ledgers and numerous prescriptions filled out with patient names" - along with almost US\$2 million in cash stored in various travel bags, as well as several gold bars and jewellery items.

Pharmacist cops ban

NSW-BASED pharmacist, Phouc Loc Le, will be barred from holding professional registration for at least 12 months, after being found guilty of facilitating the supply of prescription medications to the owner of a health foods store.

Loc Le came to the attention of the Pharmaceutical Regulatory Unit (PRU) of NSW Health, after police charged the owner of the store, Thanh Ngoc Van Trinh - his cousin after a raid of the shop uncovered goods suspected of being stolen, and a quantity of Prescription-Only medicines.

The Health Care Complaints Commission (HCCC) alleged that Loc Le had supplied the Schedule 4 products to his cousin, through a pharmacy's wholesale portal "in circumstances where he was not employed by the pharmacy, did not have express permission from the pharmacy to place orders, and did not contact the pharmacy before placing orders", using information Trinh had provided.



The HCCC claimed that Loc Le ordered large quantities of Seretide and Viagra without requesting or sighting a prescription, knowing they would be, or there was a risk they would be sold on by Trinh.

The HCCC also accused Loc Le of providing false or misleading evidence to the Pharmacy Council of NSW, by claiming not to have been aware of any previous prosecution of Trinh.

The Civil and Administrative Tribunal NSW found that Loc Le's conduct was "of sufficient seriousness to justify the suspension or cancellation of his registration".



Pharmacy Connect's Top 10

PHARMACY Connect Convenor Kos Sclavos AM has named his top 10 picks for the 2022 conference.

"Numerous sessions missed the cut, so I urge you to explore the full program at pharmacy-connect.com.au and bookmark your session preferences, based on your professional development needs and interests," he said.

- 1. Pharmacy Guild Industry Update (Fri AM)
- 2. Leadership matters (Fri AM)
- 3. mRNA Medicines a public health game changer (Fri
- 4. Electronic prescriptions: shining a light on our digital health future (Fri PM)
- 5. Community Pharmacy Industry Update (Fri PM)
- 6. The economic environment and its impact on health and pharmacy services (Sat AM)
- 7. How to ensure consumers view pharmacy as a destination for pain solution (Sat AM)
- 8. Positioning your pharmacy for success: Preparing a really useful pharmacy budget and understanding cashflow (Sat AM)
- 9. Pharmacy rentals: COVID-19 impact – where are we heading? (Sat PM)
- 10. Judy Liauw Address Hon Emma McBride MP (Sat

UK probe uncovers fake pharmacies

BRITAIN'S Medicines and Healthcare products Regulatory Agency (MHRA) has pledged to take "appropriate action" after a report on the ITV broadcast network highlighted "dozens of illegal websites posing as online pharmacies selling prescription medication".

The ITV News investigation found the fake pharmacies were selling drugs commonly sold under brand names such as Xanax. Valium and Ambien.

"Hundreds of pills can be ordered at a time, with discounts offered for bulk-buying and special promotions sent out by

email," according to ITV.

The reporters commissioned laboratory testing of the pills which found 60% of the items were mislabelled, while the websites also promise "discreet and reliable delivery" without requiring a formal prescription.

One website even explicitly stated that "all orders come complete without an overpriced prescription...we do not ask you a million questions - simply select your desired quantity and pay".

The MHRA told UK trade site Chemist+Druggist it would take immediate steps to take down illegal sites "wherever possible".



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EDITORIAL

August 2022

New Products

- **Bilastine** (Allertine) is a non-sedating, long-acting histamine antagonist with selective peripheral H₁-receptor antagonist affinity and no affinity for muscarinic receptors. Allertine is indicated for the symptomatic treatment of allergic rhinoconjunctivitis (both seasonal allergic rhinitis and perennial allergic rhinitis) and/or urticaria. Allertine tablets contain bilastine 20 mg and are available in packs of 10 or 30.
- **Diroximel fumarate (Vumerity)** reduces inflammatory responses in both peripheral and central cells and promotes cytoprotection of central nervous system cells against toxic oxidative damage, demonstrating effects on pathways known to exacerbate multiple sclerosis (MS) pathology. Preclinical studies indicate that diroximel fumarate pharmacodynamic responses appear to be mediated, at least in part, through activation of the Nuclear factor (erythroid-derived 2)-like 2 (Nrf2) transcriptional pathway, which is the primary cellular defense system for responding to a variety of potentially toxic stimuli through up-regulation of antioxidant response genes. However, the mechanism by which diroximel fumarate exerts therapeutic effects in MS is not fully understood. *Vumerity is indicated in patients with relapsing MS to reduce the frequency of relapses and to delay the progression of disability*. Vumerity is contraindicated in patients with known hypersensitivity to other fumaric acid derivatives and in suspected or confirmed progressive multifocal leukoencephalopathy. Vumerity capsules contain diroximel fumarate 231 mg and are available in packs of 120.
- Somatrogon (Ngenla) binds to the growth hormone (GH) receptor and initiates a signal transduction cascade culminating in changes in growth and metabolism. Consistent with GH signalling, somatrogon binding leads to activation of the STAT5b signalling pathway and increases the serum concentration of Insulin-like Growth Factor (IGF-1). IGF-1 was found to increase in a dose-dependent manner during treatment with somatrogon partially mediating the clinical effect. As a result, GH and IGF-1 stimulate metabolic changes, linear growth, and enhance growth velocity in paediatric patients with GH deficiency. Ngenla is indicated for the long-term treatment of paediatric patients with growth disturbance due to insufficient secretion of growth hormone. Ngenla is contraindicated in patients with active malignancy; or acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma or acute respiratory failure. Ngenla solution for injection contains somatrogon 24 mg/1.2 mL or 60 mg/1.2 mL and is available in pack sizes of one 1.2 mL prefilled pen.
- Tepotinib (hydrochloride monohydrate) (Tepmetko) is a Type I adenosine triphosphate (ATP)-competitive small molecule inhibitor of mesenchymal-epithelial transition (MET). Tepotinib inhibits HGF-dependent and independent MET phosphorylation and MET-dependent downstream signalling including the phosphatidylinositol 3-kinase/protein kinase B and mitogen-activated protein kinase/extracellular-signal regulated kinase pathways in a dose-dependent manner. Tepmetko has provisional approval for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer harbouring MET exon 14 skipping alterations. Tepmetko tablets contain tepotinib 225 mg and are available in a pack size of 60.

New Contraindications

- Acetazolamide (Diamox) is now contraindicated in severe glaucoma due to peripheral anterior synechia and haemorrhagic glaucoma.
- **Disulfiram** (Antabuse) is now contraindicated in uncompensated cardiac failure, serious organic brain damage and previous history of cerebrovascular accident.
- Esomeprazole magnesium trihydrate and amoxicillin trihydrate and clarithromycin (Nexium Hp7) is now contraindicated in hypomagnesaemia and with concomitant lomitapide.
- Isosorbide dinitrate (Isordil) is now contraindicated in acute circulatory failure (shock, vascular collapse); and aortic/mitral valve
 stenosis and disease associated with a raised intracranial pressure e.g. following a head trauma and including cerebral
 haemorrhage.
- Nirmatrelvir and ritonavir (Paxlovid) is now contraindicated with concomitant triazolam.

This list is a summary of only some of the changes that have occurred over the last month. Before prescribing, always refer to the full product information.